

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:
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Date of mailing
(day/month/year) 03 MAR 2005

Applicant's or agent's file reference

FOR FURTHER ACTION

See paragraph 2 below

4510-6-CIP-P

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US04/05751

25 February 2004 (25.02.2004)

25 February 2003 (25.02.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61B17/70 and US Cl.: 606/61

Applicant

RITLAND, STEPHEN

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/05751

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US04/05751

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-15, 21, 26-34, 36, 46-53</u>	YES
	Claims <u>16-20, 22-25, 35, 37-45</u>	NO
Inventive step (IS)	Claims <u>1-15, 26-34, 36, 46-53</u>	YES
	Claims <u>16-25, 35, 37-45</u>	NO
Industrial applicability (IA)	Claims <u>1-53</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 16-20, 22-25, 35, and 37 lack novelty under PCT Article 33(2) as being anticipated by Allard et al (U.S. Pat. No. 5,275,600). Fig. 1 of Allard et al shows a surgical implant device having all the limitations as recited in the above listed claims, including: a first rod member 14 including a beam 30, the beam further having both a circular cross section in the area immediately adjacent the end connector 18 and a non-circular cross-section between shoulders 34 and 36; a second rod member 12 including a circular opening at 22, an upper arm 24, a lower arm 24', a slot/notch 26; a means for tightening 28, and an end connector 16.

Claims 38-41 lack novelty under PCT Article 33(2) as being anticipated by Justis et al (U.S. Pat. No. 6,210,413). Fig. 4 of Justis et al shows a deformable connector device 22b having all the limitations as recited in the above listed claims, including: a disc 48 having a passageway adapted to receive a cylindrical member, a groove (slot) extending to the passageway, "skeletonized" structure 42a/42b, and truncations/indentations (at 62 and at the ring 26b mounting portion) on the exterior surface.

Claims 42-45 lack novelty under PCT Article 33(2) as being anticipated by Frigg (U.S. Pat. No. 5,002,542). Figs. 4-5 of Frigg show a connector device for a bone screw having all the limitations as recited in the above listed claims, including: a C-shaped clamp 35 having an upper section 36 with a first aperture, a lower section 37 having a second aperture aligned with the first aperture, the apertures sized to accommodate bone screw 7; a tightening screw 40; and a beam 24 interconnected to the clamp.

Claim 21 lacks an inventive step under PCT Article 33(3) as being obvious over Allard et al. Although Allard et al shows the opening to the hollow chamber in the second rod member 12 as being circular to accommodate generally cylindrical beam 30 of first rod member 14, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the beam and corresponding opening/hollow chamber to have non-circular cross-sections, such as square or rectangular, in an application where it may be undesirable to have the first and second rod members able to rotate relative to each other.

Claims 1-15, 26-34, 36, and 46-53 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest devices and methods as recited in the claims. For example, with respect to claim 1, the prior art does not teach or fairly suggest a spinal rod implant having all the limitations as recited in claims 1, including the means for tightening the claim to create a force to secure the beam within the clamp.

Claims 1-53 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.